Remarks:

Claims 4 and 48 have been amended as required by the Examiner to eliminate reference to the trade designation Nafion. Accordingly, favorable reconsideration and withdrawal of the rejection of claims 4 and 8 as indefinite under 35 U.S.C. §112, second paragraph for use of the trade designation Nafion is respectfully requested.

The Examiner rejected claims 51-53 as indefinite under 35 U.S.C. §112, second paragraph, based upon the recitation of method claims lacking any active, positive steps. These claims (and claims 28-30) depend from claim 44 (and, in the case of claims 28-30, claim 25), which is directed to a "system" (and, in the case of claim 25, an article of manufacture) and are directed to methods only due to clerical errors, which now have been corrected by amendment. Thus this rejection has been obviated and so withdrawal of this rejection is respectfully requested.

The remaining amendments set forth above merely define the invention more clearly. The claims as originally presented are believed to be patentable over the art cited in the subject Office Action and so are not believed to alter the original scope of the claims such as to add further patentable distinction over the art cited in the subject Office Action.

Favorable reconsideration is respectfully requested of the rejection of claims 1-4, 25, 27-30, and 44-53 as being anticipated by the Vachon et al. patent. All cited claims call for a bi-layer coating on an electrode. According to the claims, the bi-layer coating comprises a doped electro-active polymer layer on the electrode and a water-insoluble overlayer on the doped electro-active polymer layer. The electro-active polymer of the doped electro-active polymer

layer is doped with an ionic exchangeable releasable dopant and the overlayer is substantially impermeable to the dopant.

The Vachon et al. patent discloses "an implantable stimulation lead" having an anti-inflammatory coating on the exposed surface (col 1, lines 14-20), but Vachon et al. disclose only a single layer of polymer coating. This coating either contains an anti-inflammatory dopant (Vachon et al. claims 1-3) or is inherently biocompatible with the host (Vachon et al. claims 4 and 5). The Vachon et al. patent neither teaches nor suggests use of two layers, let alone a bi-layer configuration as called for by all pending claims. The coating disclosed in the Vachon et al. patent releases the dopant due to spontaneous release caused by an ion exchange with the surrounding environment. The Vachon et al. coating does not provide any method for controlling that release after implantation. The present application concerns a bilayer electrode wherein the outer layer is substantially impermeable to a dopant incorporated into the inner layer. The outer layer inhibits interaction between the environment and the dopant-containing inner layer, but allows for a release of the dopant upon application of a current. This allows a user to control release while substantially reducing unintended release. Vachon et al. do not disclose a similar additional layer and any dopant released according to the Vachon et a. device apparently is due to ion exchange that would be prohibited by the present application's use of an overlayer. Accordingly, Applicants believe this rejection has been traversed and respectfully request withdrawal of the rejection.

Additionally, new claims 54-57 further recite that the overlayer is substantially free of the dopant (in the case of claims 54 and 56) or any dopant (in the case of claims 55 and 57). Because the Vachon et al. device is a single-layer design, the coating disclosed by Vachon et al., when used with an anti-inflammatory dopant, contains a dopant in the outer layer. These

new claims therefore further differentiate the device of the present application from the Vachon et al. patent.

Favorable reconsideration is also requested of the rejection of claims 1-3, 26-28, 44-47, and 51-53 as being anticipated by the Phipps et al. patent. The Phipps et al. patent discloses an electrotransport device which may utilize a hydrophobic ion exchange material. However, as with the Vachon et al. patent discussed above, the Phipps et al. patent does not disclose or suggest an additional layer over the ion exchange material. Thus, contrary to the invention as defined by all subject claims, the Phipps et al. design does not include an overlayer that can inhibit unintended dopant delivery while intended dopant release is not substantially impeded. While the use of a hydrophobic ion exchange material may lessen unintended release, the exposed surface of the ion exchange material will still be affected by ion exchange with the surrounding environment, leading to unintended release of the dopant. It is not seen how such interaction can be prevented or inhibited simply by using a hydrophobic ion exchange material. Accordingly, it is submitted that claims 1-3, 26-28, 44-47, and 51-53 define patentably over the Phipps et al. patent and so withdrawal of the subject rejection is respectfully requested.

Furthermore, as noted above, new claims 54-57 further recite that the overlayer is substantially free of the dopant (in the case of claims 54 and 56) or any dopant (in the case of claims 55 and 57). Because the Phipps et al. patent discloses a design with a single layer of ion exchange material, the outer layer of that design must include a dopant. Thus, claims 54-57 further differentiate the device of the present application from the Phipps et al. patent.

Favorable reconsideration also is requested of the rejection of claims 1-4, 25, 27-30, 44-53 as being obvious in view of the Ashton et al. patent. According to the Examiner, the degree of hydrolyzation of the polymer to control the release of an active ingredient is a matter of

design. The Ashton et al. patent discloses a non-electrode implantable device which utilizes the permeability of an outerlayer to control the release of a therapeutic agent. The Examiner contends that a determination of the permeability as utilized in the present invention is an obvious matter of design and would only require experimentation from Ashton et al.'s principles to accomplish the device taught by the present application. However, if a person having ordinary skill in the art experimented upon the principles disclosed in the Ashton et al. patent to achieve an outer layer substantially impermeable to the therapeutic agent, the utility of the device would be destroyed. "[I]f the teachings of a prior art reference would lead one skilled in the art to make a modification which would render another prior art device inoperable, then such a modification would generally not be obvious." *In re Kramer*, 925 F.2d 1479 (Fed. Cir. 1991). In contrast to the present application, Ashton et al. do not envision the use of an electrode to stimulate release upon demand. Without the means to stimulate release, Ashton et al.'s device would be relatively inert upon implantation and thus the utility would be destroyed.

Furthermore, claims 1, 25, and 44 call for the presence of an electrode in contact with the electro-active polymer inner layer. This further distinguishes the present invention from the implantable device disclosed in the Ashton et al. patent because the Ashton et al. patent depends upon ion exchange caused by the surrounding environment to deliver its therapeutic agent. Without the use of a source of current, the present application would not deliver an efficacious amount of dopant, as the mechanism depended upon by the Ashton et al. patent is inhibited by an overlayer. It is therefore submitted that the subject claims define patentably over the Ashton et al. patent and withdrawal of the subject rejection is respectfully requested.

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all

presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, he is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment is respectfully requested.

Respectfully submitted,

Kenneth Solomon, Reg. No. 31,427
Thompson Coburn LLP
One US Bank Plaza
St. Louis, Missouri 63101
Telephone: 314-552-6297
Fax: 314-552-7297